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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,856	12/31/2001	Dilip Wagle	361331-507	4036
30623	7590	11/15/2004	EXAMINER	
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C. ONE FINANCIAL CENTER BOSTON, MA 02111			DELACROIX MUIRHEI, CYBILLE	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 11/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/036,856

Applicant(s)

WAGLE ET AL.

Examiner

Cybille Delacroix-Muirheid

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) 3 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 4-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Detailed Action

The following is responsive to Applicant's election received Dec. 22, 2003.

Applicant's election of 2,4,5-trimethylthiazole with traverse is acknowledged. However, since Applicant has not specifically pointed out the alleged errors in the requirement mailed Dec. 1, 2003, it is maintained for reasons already of record.

Claims 1-7 are currently pending.

Claim 3 is withdrawn from consideration as being drawn to a non-elected species.

Claim Objection(s)

1. Claims 1 and 7 are objected to because of the following informalities: in claims 1 and 7, the "{.....}" and "(.....)" should be deleted and replaced with appropriate punctuation. Additionally in claim 1, the Examiner respectfully requests that Applicant delete "including a human" since descriptions of examples or preferences is properly set forth in the specification rather than the claims. Appropriate correction is required.

Claim Rejection(s)—35 USC 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-2, 4-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, page 33, lines 13-15, the phrase "at least one compound of formula I administered in effective amount is not a thiazole substituted on a ring carbon

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sulfonamide (the amide of which can be substituted) that has carbonic anhydrase inhibiting activity” is vague and indefinite. It is not clear whether the limitation within the parenthetical is considered a limitation in the claim. Furthermore, the limitation of the “ring carbon sulfonamide” appears to have no antecedent basis within the claim. To what portion of the compound structure does “ring carbon sulfonamide” refer?

Clarification is respectfully requested.

Claim Rejection(s)—35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-2, 4-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Wagle et al, 2002/0022622 A1.

Wagle et al. disclose a method of treating diabetic retinopathy in a patient by administering, topically to the eye of the patient, an effective amount (0.01 to about 0.8%w/v; 0.1 or 0.5 to 4 mg/kg body weight daily) of a thiazole compound, preferably 2,4,5-trimethylthiazole. Please see [0126]; [0139]; [0096]; [0098]; [0275]; [0278]; [0282].

The claims are anticipated by Wagle et al. because Wagle et al. teach administration of an identical active agent, i.e. 2,4,5-trimethylthiazole, in identical effective amounts (see specification page 20, lines 23-27; page 21, lines 22-23)to a

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host in need thereof, i.e. patient suffering from diabetic retinopathy, (please see specification page 1). Therefore, a decrease in intraocular pressure or an improvement in ocular accommodation in the patient would be an inherent characteristic of the disclosed method.

Conclusion

Claims 1, 2, 4-7 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybillie Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **703-872-9306**.

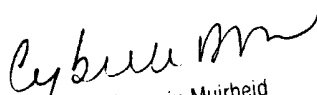
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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CDM 
Nov. 10, 2004


Cybille Delacroix-Muirheid
Patent Examiner Group 1600